

Technical Data Sheet CB036

Acne correcting gel / Acne correctiegel / Gel correcteur d'acné

Information to the pharmacist:

While HeW Pharma BV is the original manufacturer of this product, the pharmacist remains the end responsible person for the quality of each individual unit. Under Belgian law, any act of refilling of a bulk product or addition of any ingredient to a bulk product is considered manufacturing. You are required by law to correctly label and notify the resulting end product (either refilled bulk product as such or processed bulk product).

Notification of your end product can be performed at the Cosmetic Products Notification Portal (CPNP) via the following steps:

- Create an EU Login in account following the step on the following web site: [CPNP - How to create an EU Login account? \(europa.eu\)](http://europa.eu/CPNP-How-to-create-an-EU-Login-account/)
- Make an account via the following web site <https://webgate.ec.europa.eu/cpnp/public/ecascreate.cfm> and log in.
- Follow the tutorial: http://ec.europa.eu/growth/sectors/cosmetics/cpnp_en

Information to add in the CPNP

Product Name: Acne correcting gel / Acne correctiegel / Gel correcteur d'acné

Product imported in the Community: no

Member state of first placing on the market: Belgium

CMR substances of category 1A or 1B present: Not present.

Nano materials present: Not present.

Category of cosmetic product: Level 1: Skin products. Level 2: Skin care products. Level 3: Face care products other than face mask.

Physical form: cream/paste

Formulation name: Skin Care Cream, Lotion, Gel

PREDEFINED FRAME FORMULATION (to be used for CPNP): 1.1 -2013.

<https://webgate.ec.europa.eu/cpnp/resources/ff/FF-2013-EN-TRA-00.pdf>

Glycols and glycol ethers present: Not present.

Hydrocarbon solvents present: Not present.

Alcohols other than ethanol and isopropanol present: Not present.

Vitamine A or its derivatives: Not present.

Xanthines present: Not present.

Total levels of essential oils, camphor, menthol or eucalyptus present: Not present.

Toxicity information: None.

Label needs to be added

Note that the following information is mandatory on the label:

- Name of the product
- Function of the product
- List of ingredients with INCI name
- Nominal content
- Name & address of the responsible person
- Mode of use when applicable
- Only supported claims can be added on the label
- Batch number
- Expiry date (not mandatory if shelf life is > 30 months)
- Period after opening

INCI : Aqua, Glycerin, Squalane, Arachidyl Alcohol, Sclerotium Gum, Gaultheria Procumbens (Wintergreen) Leaf Extract, Niacinamide, Glycery Laurate, Mandelic Acid, Saccharum Officinarum (Sugar Cane) Extract, Coleus Forskohlii Root Oil, Aloe Barbadensis Leaf Juice, Olea Europaea (Olive) Oil, Zingiber Officinale (Ginger) Extract, Sodium Dilauramidoglutamide Lysine, Behenyl Alcohol, Arachidyl Glucoside, Kaolin, Myristyl Alcohol, Disodium EDTA, Myristyl Glucoside, Tocopherol, Helianthus Annuus (Sunflower) Seed Oil, Phytic Acid, Caprylyl Glycol, Sodium Hydroxide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Ammonium Acryloyldimethyltaurate/Vp Copolymer, Octadecyl Di-T-Butyl-4-Hydroxyhydrocinnamate, Phenoxyethanol, Decylene Glycol

Suggested application: If necessary, dab on the pimple with the applicator tip, ideally after the balancing day cream. If using in the morning, apply sunscreen afterwards. For external use only.

Use and dosage: If necessary, dab on the pimple with the applicator tip, ideally after the balancing day cream. If using in the morning, apply sunscreen afterwards.

Supported claims: Sebum regulation, healing property, pigmentation reduction, acne management, anti-scarring, anti-imperfections, anti-recurrence,

Compatibility test on packaging:

The product has been tested on polypropylene plastic packaging both at room temperature and at 40 °C. No effects of packaging on the products qualities were observed.

Characteristics

Appearance: White-offwhite gel

Color: White-offwhite

Odor: Characteristic (no added perfume)

Viscosity: 750-1500 mPa.S-1 measured with an R-3 spindle at 250 rpm, room temperature.

pH value: 4,8-5,1

Preservative: Phenoxyethanol

PAO (Period After Opening): 12M

Shelf life: 36M

Storage conditions: Dark, at Room Temperature

Allergens:

- None (as per Annex III of the Cosmetics Regulation 1223/2009).

Other information:

- Contains 99.42% ingredients of natural origin.
- +/- 1% Physiological variation can appear on the final product due to the naturalness of the raw materials used.
- The color of the gel can become darker over time due to the naturalness of the raw materials used.

NOTE: In our formulations, heavy metal, petrolatum, propylene glycol, isopropyl alcohol, isothiazolinones, parabens, gluten, genetically modified organisms are excluded. Nickel <1 p.p.m. Products can undergo modifications and variations to improve their functionality. In particular, the use of active principles and plant extracts, although obtained with standardized methods, it can change the color and smell of the products for the impossibility of obtaining vegetable crops equal to each other.

Overview:

The Acne Correcting Gel is a purifying gel that prevents the formation of new impurities and makes existing pimples disappear faster without scarring. It has a proven anti-bacterial effect against the bacteria that can cause acne. The combination of active ingredients results in a complete approach. Thus, they reduce sebum production, work exfoliating, have an anti-bacterial effect and promote skin recovery.

Active ingredients:

Monolaurin (coconut extract) is active against *C. Acnes*, the bacteria involved in acne.

Niacinamide or vitamin B3 has antioxidant and anti-inflammatory properties. Moreover, it also reduces sebum production and hyperpigmentation that may remain after acne. It also improves the skin barrier by increasing collagen and ceramides production.

Mandelic acid is an AHA (alpha hydroxy acid) that removes dead skin cells in the top layer of the skin. Thus, it acts exfoliating, causing scars to fade faster and the skin to look more radiant.

Ginger extract contains antioxidants and active ingredients that soothe inflammation. Moreover, it also acts antibacterial. Thus, it helps keep pores clear and fight *C. acnes*.

Aloe vera, derived from the leaves of the *Aloe barbadensis* plant, has soothing and antioxidant properties. In addition, it also stimulates wound healing by boosting collagen production and strengthening the collagen network in the skin.

Wintergreen with natural salicylic acid. Salicylic acid is a BHA (beta hydroxy acid) that is exfoliating. This helps with acne to dissolve clogged pores and remove excess dead skin cells and sebum.

Suitable for vegans.

Dermatologically tested.

General properties: The Acne Spot Correction Gel is an effective nutrient composite offering a multi-pronged approach to acne management by addressing the various skin concerns that come with acne. The cosmeceutical blend of monolaurin, coleus oil, policosanol, niacinamide, mandelic acid, ginger extract, aloe vera and salicylic acid not only has keratolytic, anti-bacterial, antiinflammatory,

anti-irritating, and anti-scarring properties, but also has skin regenerating, soothing and moisturizing properties in order to address all possible symptoms of acne. Prevents blemishes and scarring, with ginger extract and niacinamide for normal to acne-prone skin. It reduces sebum production and inflammation while minimizing recurrence of acne break outs. Suitable for sensitive skin.

Efficacy, safety and other in vitro and in vivo tests:

All stability, microbial challenge and safety assessments and tests have been performed and documented as required in the Product Information Dossier.

Disclaimer:

HeW Pharma BV does not support nor recommends the use of other claims to this product.

HeW Pharma BV cannot be held responsible for any incorrect information on final labelling or as a result of marketing of the final product.

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